

PSJ2 Exh 118

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and among the United States Attorney's Office for the District of Maryland, acting on behalf of the United States, the Drug Enforcement Administration ("DEA") for the Washington Division, and CVS Pharmacy, Inc. and all of its subsidiaries and affiliates (collectively "CVS") (each a "Party" and collectively the "Parties").

RECITALS

- A. CVS Pharmacy, Inc. is a Rhode Island corporation with its corporate headquarters in Woonsocket, Rhode Island. CVS, directly or through its retail pharmacy subsidiaries and affiliates, and through its CVS/pharmacy division, operates retail pharmacies in the State of Maryland that dispense prescription drugs, including controlled substances, to retail consumers (hereafter referred to as "CVS/pharmacy retail stores").
- B. Each CVS pharmacy retail store in Maryland is separately registered with DEA and is assigned a unique DEA registration number that authorizes it to dispense controlled substances pursuant to the provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("CSA"), and its implementing regulations. The CVS/pharmacy retail stores located in Maryland will be referred to collectively herein as "Maryland CVS/pharmacy retail stores."
- C. CVS acknowledges that all of its DEA-registered CVS/pharmacy retail stores were and are required to comply with the CSA and the regulations promulgated thereunder.
- D. The CSA prohibits the distribution of a controlled substance without a valid prescription. 21 U.S.C. § 842(a)(1). To be valid, a prescription must be issued for a

legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. 21 C.F.R. § 1306.04.

E. CVS acknowledges that it has a corresponding responsibility to dispense only those prescriptions that have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and that knowingly filling a prescription not in the usual course of professional treatment or in legitimate and authorized research subjects CVS to penalties under the CSA. 21 C.F.R. § 1306.04.

F. The United States contends that CVS failed to fulfill its corresponding responsibility under 21 C.F.R. § 1306.04 and thus is subject to civil penalties under 21 U.S.C. § 842(a)(1) and § 842(c)(1).

G. CVS acknowledges that certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations by not conducting “corresponding responsibility” when dispensing certain controlled substances in some instances between 2008 and 2012.

H. At all times relevant herein, the CSA authorized the imposition of civil penalties for each of the categories of Covered Conduct as described in paragraph 2 below.

To avoid the delay, expense, inconvenience, and uncertainty of litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-H set forth above are fully adopted herein.
2. For purposes of this Agreement, “Covered Conduct” shall mean the following:

Maryland CVS/pharmacy Retail Stores

(i) Failure of any Maryland CVS/pharmacy retail store, on or before the Effective Date of this Agreement, to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04;

(ii) Dispensing, on or before the Effective Date of this Agreement, by any Maryland CVS/pharmacy retail store of controlled substances to individuals CVS knew or should have known were diverting controlled substances;

(iii) Refusal or negligent failure, on or before the Effective Date of this Agreement, by any Maryland CVS/pharmacy retail store to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under subchapter I or subchapter II of the CSA and the CSA's implementing regulations, including, but not limited to, failure by any Maryland CVS/pharmacy retail store to comply with the record-keeping obligations contained in 21 C.F.R. Part 1304; and

(iv) Conduct by any Maryland CVS/pharmacy retail store that occurred on or before the Effective Date of this Agreement and that is inconsistent with or in violation of the CSA and/or its implementing regulations.

3. CVS shall pay to the United States the total sum of \$8,000,000.00 (eight million dollars and no cents) (the "Settlement Amount") within ten (10) business days after the

Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to CVS by the United States Attorney's Office for the District of Maryland.

4. In consideration of the undertakings of the United States contained herein, CVS fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that CVS has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that CVS reserves and does not release any liability based on obligations created by this Agreement.

5. In consideration of the undertakings by CVS, and subject to the exceptions in Paragraph 6 below (concerning excluded claims), and conditioned upon CVS's full payment of the Settlement Amount, the United States Attorney's Office for the District of Maryland, acting on behalf of the United States, and the DEA for the Washington Division agree to:

(i) Release and refrain from instituting any administrative claims against CVS or any of its subsidiaries or affiliates and any of the officers, directors, employees, agents, successors, and assigns of each, arising from or related to the Covered Conduct;

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. § 842 based on, arising from, or related to the Covered Conduct.

6. Notwithstanding the releases given in Paragraph 5 of this Agreement, the United States specifically reserves and does not release:

- (i) Any federal criminal liability;
- (ii) Any criminal, civil, or administrative claim arising under Title 26, United States Code (Internal Revenue Code);
- (iii) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and
- (iv) Any liability based on obligations created by this Agreement.

7. Nothing in this Agreement constitutes an Agreement by the United States Attorney's Office concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein. This Agreement is specifically limited to the Office of the United States Attorney for the District of Maryland and the DEA for the Washington Division and cannot bind other federal, state, or local authorities and jurisdictions.

9. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she, or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Maryland. For purposes of construing this Agreement,

the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

12. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

13. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

14. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form of signature, each of which constitutes an original and all of which constitute one and the same Agreement.

15. This Agreement inures to the benefit of and is binding on each Party and its respective successors, transferees, heirs, and assigns.

16. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

17. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). The United States agrees to notify CVS immediately when the final signatory has executed this Agreement.

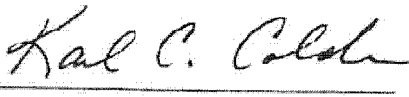
[Signatures begin on next page.]

ON BEHALF OF THE UNITED STATES OF AMERICA:



Thomas F. Corcoran
Assistant U.S. Attorney
United States Attorney's Office
District of Maryland

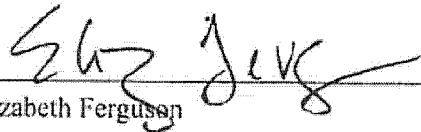
DATE: 2/12/2016



Karl Colder
Special Agent in Charge
Drug Enforcement Administration,
Washington Division

DATE: 2/8/2016

ON BEHALF OF CVS PHARMACY, INC.:



Elizabeth Ferguson
Senior Vice President, Assistant General Counsel
CVS Pharmacy, Inc.

DATE: 2/5/2016